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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,279	04/16/2007	Keiichi Takagaki	4364.P0018US	5985

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EXAMINER

ARIANI, KADE

ART UNIT	PAPER NUMBER
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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,279	Applicant(s) TAKAGAKI ET AL.	
	Examiner KADE ARIANI	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 1 and 2 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1 and 2 are pending in this application and were examined on their merits.

Claim Objection

Claims 1 and 2 are objected to because of the following informalities:

An indefinite article (“a” or “an”) is used before singular nouns that refer to any member of a group, and a definite article (“the”) is used before singular and plural nouns that refer back to a particular member of a group.

In claim 1 “xylanase”, “glycosaminoglycan”, and “proteoglycan” lack the proper definite article “a”, and in claim 2 “xylanase” lacks the proper definite article “the”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 provide for a method for separation of a glycosaminoglycan which comprises using xylanase for separation of glycosaminoglycan from core protein of

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proteoglycan, but, since the claims do not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Takagaki et al. (The Journal of Biological Chemistry, May 2002, Vol. 277, No. 21, p.18397-18403).

Claim 1 is drawn to a method for separation of glycosaminoglycan which comprises using xylanase for separation of glycosaminoglycan from core protein of a proteoglycan.

Takagaki et al. disclose a method for separation of a glycosaminoglycan which comprises using a xylanase that cleaves the linkage between a glycosaminoglycan chain and its core protein (See Abstract, lines 1-4, and p.18399, 1st column 2nd paragraph, Results lines 1-7).

Takagaki et al. therefore clearly anticipate the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takagaki et al. (The journal of Biological Chemistry, May 2002, Vol. 277, No. 21, p.18397-18403) in view of Kaneko et al. (Biosci. Biotechnol. Biochem., 2000, Vol. 64, No.2, p.447-451).

Claims 1 and 2 are drawn to a method for separation of a glycosaminoglycan which comprises using a xylanase for separation of glycosaminoglycan from core protein of a proteoglycan, wherein the xylanase is derived from *Streptomyces olivaceovirdis*.

As mentioned immediately above, Takagaki et al. teach a method for separation of a glycosaminoglycan which comprises using a xylanase that cleaves the linkage between a glycosaminoglycan chain and its core protein (See Abstract, lines 1-4, and p.18399, 1st column 2nd paragraph, Results lines 1-7).

Takagaki et al. teach an endo-type glycosidase enzyme activity is able to cleave the internal xylosyl serine linkage between a core protein and a GAG chain. Takagaki et al. teach such enzyme is a useful tool for isolating glycosaminoglycan chains from the peptides (p.18397 2nd column 2nd paragraph lines 12-16).

Takagaki et al. do not teach the xylanase is from *Streptomyces olivaceovirdis*. However, Kaneko et al. teach a β -xylanase (EC 3.2.1.8) from *Streptomyces olivaceovirdis*, and the hydrolysis of β -1, 4-glycosidic linkages within the xylan backbone by the xylanase (Abstract, p.447 1st column 1st paragraph).

Therefore, in view of the above teachings, it would have been obvious to one of ordinary skill in the art to modify the method as taught by Takagaki et al. by substituting the xylanase (endo-type glycosidase) in Takagaki et al. method with the xylanase (endo-type glycosidase) as taught by Kaneko et al. The motivation as taught by Takagaki et al. would be that a xylanase with endo-type glycosidase activity was able to cleave the internal xylosyl serine linkage between a core protein and a GAG chain, and thus would enable the release of glycosaminoglycans from glycosaminoglycan peptides.

The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art, and because the substitution of one known xylanase for another would have yielded the predictable results of hydrolyzing the linkage between a core protein and a glycosaminoglycan chain to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/MICHAEL G WITYSHYN/
Supervisory Patent Examiner, Art Unit 1651